

her previous rejection based on enablement grounds. However, all claims stand finally rejected, as follows:

Claims 1-12, 25 and 26 stand rejected under 35 U.S.C. § 112, first paragraph, as containing new matter as a result of the amendment submitted in response to the previous Office Action;

Claims 1-4, 6, 7 and 25 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,571,410 to Swedberg et al. in view of U.S. Patent No. 4,654,127 to Baker et al.;

Claims 5, 8, 9 and 26 stand rejected under 35 U.S.C. §103(a) as obvious over Swedberg et al. in view of Baker et al. and U.S. Patent No. 5,968,331 to Kambara et al.; and

Claims 10-12 stand rejected under 35 U.S.C. §103(a) as obvious over Swedberg et al. in view of Baker et al., Kambara et al., and U.S. Patent No. 5,641,440 to Kaltenbach et al.

The rejections are addressed in part by the above amendments to the claims and are otherwise traversed for reasons which will be discussed in detail below.

THE ABOVE AMENDMENTS:

Claims 1 and 25 have been amended to clarify that the reservoir unit having one or more reservoirs has dimensions compatible with the separation unit for operative and modular coupling **in fixed alignment**. Support for these amendments is found, e.g., on page 7, line 16-19, wherein it is disclosed that operative coupling involves two pieces held in "dimensionally fixed relationship," and on page 18, lines 5-7, wherein it is disclosed that the various parts of the inventive apparatus are preferably formed "to facilitate efficient alignment for coupling." As the amendments are supported by the original disclosure, no new matter has been added.

Claims 13-24 and 27 have been cancelled as non-elected claims in response to the previous restriction requirement. As such, cancellation is without prejudice, without intent to acquiesce in any rejection, and without intent to abandon any originally claimed subject matter.

THE REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH:

Claims 1-12, 25 and 26 were rejected under 35 U.S.C. § 112, first paragraph, on the ground that applicants' previous amendment adds new matter. Specifically, the Examiner has stated that pages 10, line 14, to page 11, line 17, does not disclose a driving force which results from the simultaneous operative and modular coupling. Instead, the Examiner asserted that these pages describe "a membrane covering the reservoirs which can be punctured by a protrusion arm on the separation unit which allows fluid 'to flow' from the reservoir into the separation unit." The Examiner continued by contending that "the only 'driving force' described in the specification results from the power unit 110 and probes for applying the driving force to drive movement of chemicals from the reservoir through the microchannel."

Applicants disagree because the Examiner's own statement indicates the amendment is supported by the specification as filed. The Examiner has acknowledged that coupling the separation unit with the reservoir unit allows the protrusion arm of the separation unit to penetrate the membrane of the reservoir unit, thereby resulting in fluid flow from the reservoir to the separation unit. Since a fluid does not flow unless a force acts upon the fluid, the disclosure relating to fluid flow explicitly provides support for a driving force. In addition, it is evident that from the figures accompanying the cited text that modular and operative coupling of the reservoir unit and the separation unit may be carried out simultaneously. Thus, no new matter was introduced and rejection on this basis should be withdrawn.

THE 35 U.S.C. §103(A) REJECTION OVER SWEDBERG ET AL. IN VIEW OF BAKER ET AL.:

Claims 1-4, 6, 7 and 25 have been rejected again as obvious over Swedberg et al. in view of Baker et al. The Examiner repeated reasoning from the previous Office Action that it would have been obvious to one skilled in the art at the time of the invention to include prepackaged liquid reagents in the apparatus of Swedberg et al. in order to avoid contaminating the reagents before introduction into the microchannel and to eliminate the need for handling of calibrated reagents. In addition, the Examiner seems to have characterized the amendment submitted in response to the previous office action as merely introducing an intended-use limitation. Finally,

No
in response
to the argument
that Baker does
not have a separation
unit

the Examiner asserted that Baker et al.'s disclosure relating to the turning of a fluid reservoir to a "start position" reads on simultaneous operative and modular coupling as claimed.

The applicants again disagree and submit that the three basic criteria for *prima facie* obviousness have not been met. As stated before, it appears that the Examiner employed improper hindsight analysis in issuing this rejection because there is no reason as to why Swedberg et al. should be read with Baker et al. In addition, with respect to the Examiner's assertion that Baker et al. discloses simultaneous operative and modular coupling, it is evident that the opposite is true. Baker et al. is directed to a device that requires an action distinct from simultaneous operative and modular coupling in order to allow fluid to flow from the reservoir. For example, Baker et al. discloses that a cylindrical reservoir is mounted within a sleeve of an analytical unit and then rotated. See column 4, line 38 to column 5, line 50. In addition, Baker et al. requires turning of the reservoir unit to a "start position" before the device is inserted into the receptacle, see column 5, lines 21-27. Thus, there is no disclosure in either Baker et al. or Swedberg et al. relating to simultaneous operative and modular coupling. At best, the combination of Baker et al. and Swedberg et al. teaches a device wherein modular coupling and operative coupling, i.e., inserting and turning, are two events that do not occur simultaneously. Since the teaching of simultaneous operative and modular coupling is absent from both Swedberg et al. and Baker et al., the rejection was issued in error and withdrawal is requested.

In addition, all pending claims have now been amended to clarify that the reservoir unit of the present invention has dimensions compatible for operative and modular coupling in fixed alignment with the separation unit. This element relates to the dimensions of the reservoir unit and thus represents a structural limitation to the inventive device. As such, this amendment cannot be characterized as introducing a mere intended-use limitation. Moreover, there is no disclosure in either Swedberg et al. or Baker et al. relating to coupling between the separation unit and the reservoir unit in fixed alignment. Instead, Baker et al. teaches away from a reservoir in fixed alignment with separation unit because the reservoir unit of Baker et al., as pointed out by the Examiner, is rotatable, not fixed. Thus, the combination of Swedberg et al. and Baker et al. cannot render the present invention obvious.

hindsight
the turns of the cylinder go to a test position allows for one flow or fluid in the reservoir to flow

37

For the above reasons, *prima facie* obviousness has not been established and the rejection is in error. Reconsideration and withdrawal of the rejection is accordingly respectfully requested.

THE REJECTION UNDER 35 U.S.C. §103(A) OVER SWEDBERG ET AL. IN VIEW OF BAKER ET AL. AND KAMBARA ET AL.:

Claims 5, 8, 9 and 26 have been again rejected as obvious over Swedberg et al. in view of Baker et al. and Kambara et al. as applied to claim 2, the Examiner referring to the previous Office Action. The Examiner previously contended that it is obvious to include in the apparatus of Swedberg et al. and Baker et al. probes to drive liquid into microchannels in order to reduce the time and labor needed to introduce the liquids in the microchannels.

As before, applicants respectfully disagree. The rejected claims all depend from independent claim 1 which, as discussed above, is nonobvious over Swedberg et al. and Baker et al. as neither patent teaches that a driving force may result from simultaneous modular and operative coupling in fixed alignment. The addition of Kambara et al. does not provide any further teaching or suggestion of such a driving force resulting from **simultaneous modular and operative coupling in fixed alignment** and therefore provides no additional basis for the rejection of the independent claim. In fact, Kambara et al. is directed to a sample injecting device for an electrophoresis apparatus, wherein an electric field is applied to inject the sample electrophoretically into the gel in an electrophoresis separation capillary. As disclosed in column 8, lines 34-40 of Kambara et al., the electric field is not applied until after the device is assembled. Thus, this patent also teaches away from simultaneous modular and operative coupling to provide a driving force to supply liquid reagents and analyte.

As the references in combination fail to disclose each and every element of the claims, they represent an improper basis for a §103(a) rejection. Reconsideration and withdrawal of the rejection is thus requested.

Kambara
is re-open
for the teaching of
a probe to
to produce an
electric field
to drive the
a driving force
to drive the
microchannels

THE REJECTION UNDER 35 U.S.C. §103(A) OVER SWEDBERG ET AL. IN VIEW OF BAKER ET AL., KAMBARA ET AL. AND KALTENBACH ET AL.:

Claims 10-12 were again ejected as obvious over Swedberg et al. in view of Baker et al., Kambara et al. and Kaltenbach et al., the Examiner citing Swedberg et al., Baker et al. and Kambara et al. as before with reference to the previous Office Action. The previous rejection stated that the addition of the peltier plate recited in these claims would have been obvious to one skilled in the art given the teaching of Kaltenbach et al. As before, applicants disagree. The rejected claims depend from independent claim 1 which is nonobvious over Swedberg et al., Baker et al. and Kambara et al. for the reasons discussed above. The addition of Kaltenbach et al. does not provide any further teaching or suggestion of simultaneous modular and operative coupling of the reservoir unit and the separation unit **in fixed alignment** and therefore provides no additional basis for the rejection of the independent claim. As the rejected claims all depend from a nonobvious claim, they too are nonobvious. Reconsideration and withdrawal of the rejection is thus requested.

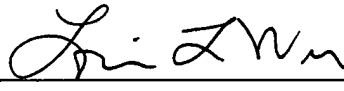
CONCLUSION

For all of the above reasons, it is submitted that the application comports with all requirements of 35 U.S.C. §112, and that the pending claims define an invention that is patentable over the art. As the application is now in condition for allowance, a prompt indication

to that effect would be appreciated. Should the Examiner have any questions concerning this communication, she is welcome to contact Mike Beck at (650) 485-3864.

Respectfully submitted,

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Date

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